

REMARKS

Before entry of this Amendment, claims 1-26 were pending in the application and claims 27 and 28 were canceled. After entry of this Amendment claims 29, 30 and 31 have been added, claims 1-11 and 13 – 26, remain pending under examination, and claims 12, 27 and 28 are canceled. Claims 4 and 18 have been amended to become independent claims. The number of total claims has not been increased beyond the number for which payment previously had been made, and the number of independent claims has not been increased beyond the number for which payment previously had been made.

Applicant has carefully considered the Examiner's Action of February 2, 2009, and the references cited therein. The following is a brief summary of the Action. Claims 1-3, 5-11, 13-19, 21-24 and 26 were rejected under 35 U.S.C. 102(b) as being anticipated by Williamson (USP 5,545,179). Claims 4 and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson. Claim 20 was rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Buckholtz et al (USP 5,409,006). Claim 25 was rejected under 35 U.S. C. 103(a) as being unpatentable over Williamson in view of Taylor (USP 5,935,107). Objection was made to claims 1, 6 and 8 due to a lack of antecedent basis for "the end" or "the catheter shaft."

Applicant has amended claims 1, 6 and 8 to provide antecedent basis for "the end" and "the catheter shaft." Accordingly, withdrawal of the objections to claims 6 and 8 is respectfully requested.

For the reasons explained below, applicant respectfully traverses the rejection of claims 1-3, 5-11, 13-19, 21-24 and 26 under 35 U.S.C. 102(b) over Williamson.

The present invention pertains to a device for tamponade of body cavities and mechanical anchoring of a catheter. To tamponade a body cavity means to fill that cavity.

Claim 1 has been amended to add the feature of claim 12. Page 4 of the February 2009 Office Action concedes that Williamson lacks the limitation of claim 12.

Claim 18, which has been amended to become an independent claim, requires a clamping closure having a longitudinally displaceable sleeve slidably attached to the tube segment. Williamson fails to disclose any such feature.

Applicant therefore respectfully submits that claims 1-3, 5-11, 13-19, 21-24 and 26 are patentable under 35 U.S.C. § 102(b) over Williamson.

For the reasons explained below, applicant respectfully traverses the rejection of claims 1 and 4 under 35 U.S.C. 103(a) as being unpatentable over Williamson.

Page 4 of the February 2009 Office Action concedes that Williamson lacks the limitations of each of claims 1 and 4 concerning, respectively, the greater thickness of the inner wall and the transparent material forming the tube segment. However, page 4 of the February 2009 Office Action dismisses these features “as the applicant has not shown that they provide any advantage or solve any problem.”

However, by having the inner wall formed of a greater wall thickness than the outer wall as required by claim 1, as presented herein, the introduction of fluid between the two walls follows the path of least resistance and expands the outer wall. Moreover, the internal area defined by the inner wall is more likely to remain receptive to the insertion of a catheter or other surgical implement without fear of puncture of the inner wall due to the inner wall having collapsed upon itself from the fluid introduced between the two walls. As shown by Fig. 10 of Williamson, the inner wall of Williamson collapses upon itself, which contrasts with the structure illustrated in applicant’s Figs. 1 – 6.

As to claim 4, the transparency of the tube material as required by claim 4 permits viewing through the tube segment. Additionally, the transparency of the tube material as required by claim 4 permits the use of a light element that can remain within the tube segment, and thus shielded from being soiled by blood and other body substances that would diminish the light available to illuminate the body cavity. Both of these capabilities are useful as either a light, camera, or endoscope is inserted through the tube segment and directed at a portion of the body cavity that is most advantageously viewed through the tube segment. This would include regions where the tube segment was touching or pressed against the inside-facing surface of an organ or other body tissue.

Williamson fails to appreciate any of the above advantages attendant either the greater wall thickness or the transparent material forming the tube segment.

Applicant therefore respectfully submits that claims 1 and 4 are patentable under 35 U.S.C. § 103(a) over Williamson.

For the reasons explained below, applicant respectfully traverses the rejection of claim 20 under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Buckholtz et al.

Buckholtz et al fails to correct the deficiency noted above in Williamson. Moreover, claim 20 requires the pressure sensor to be contained **in an interior space of the tube segment**, which must be **inflatable** to assume a **torus geometry** with the inner wall defining an internal area.

The paragraph that bridges pages 4 and 5 of the February 2009 Office Action states:

Williamson discloses all of the limitations recited in the independent claim but fails to disclose a pressure sensor. Buckholtz discloses that pressure sensors are beneficial in medical access devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Williamson with the pressure sensor of Buckholtz to make a securement device that could make sure the appropriate inflation pressure was present.

However, disclosing that pressure sensors are beneficial in medical access devices falls short of suggesting or disclosing a particular placement in a particular construction of a medical device. Buckholtz fails to disclose placement of a pressure sensor in the **interior space** of an **inflatable tube segment** that assumes a **torus geometry** with the inner wall defining an internal area. As shown in Buckholtz Fig. 3, placement of a pressure sensor 35 should be done on the rigid catheter tube 30, not on the balloon 22. Accordingly, Buckholtz teaches away from applicant's claimed invention.

Applicant therefore respectfully submits that claim 20 is patentable under 35 U.S.C. § 103(a) over Williamson in view of Buckholtz et al.

For the reasons explained below, applicant respectfully traverses the rejection of claim 25 under 35 U.S.C. 103(a) as being unpatentable over Williamson in view of Taylor.

Taylor et al fails to correct the deficiency noted above in Williamson. Moreover, lines 7-10 on page 5 of the February 2009 Office Action contend that (emphasis added):

Taylor discloses that is well known in the medial access device art to include an electrode. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention **to modify the device of Williamson with the electrode of Taylor.**

However, as explained below, **the electrode of Taylor et al** does not satisfy claim 25, which requires a pair of electrodes affixed to a surface of the tube segment, which must be **inflatable** to assume a **torus geometry**.

Taylor et al pertains to a gastrostomy tube 10, the distal end 36 of which being illustrated in Taylor et al Figs. 2 and 3. An anchor 50 is formed integral with the walls at the distal end 36 of the tubular member 30 of the gastrostomy tube 10. The anchor 50 is formed as a Malecot structure that includes multiple equally spaced expansion sections 52-58 shown in Fig. 3. Taylor et al's gastrostomy tube 10 is not inflatable to assume a torus geometry.

Taylor et al does not call for the provision of any electrode 83 affixed to a tube segment that is **inflatable** to assume a **torus geometry**. Instead, Taylor et al calls for providing an obturator 25 that is separate from Taylor et al's gastrostomy tube 10. Taylor et al's obturator 25 has at the obturator's smaller diameter section 74 a distal end 76 that has an operative tip 81, which includes an electrode 83 that is electrosurgically energized. Taylor et al column 5, lines 3-13. As explained at Taylor et al column 5, lines 41-46, the electrode 83 is energized to penetrate the abdominal wall 14 and stomach wall 18 of the patient so that the electrode 83 passes through the walls 14, 18 to create a path through which the gastrostomy tube 10 can be moved into the patient's stomach. Thus, the electrode 83 disclosed in Taylor et al performs the function of burning through the patient's flesh to create an opening through which the tube segment of the anchor 50 can be passed. As explained at Taylor et al column 5, lines 50-52, the obturator 25 is thereafter removed from the gastrostomy tube 10, and the electrode 83 of course also becomes removed. Thus, the Taylor et al obturator 25 with the electrode 83 is not a device for tamponade of body cavities and for mechanical anchoring of a catheter.

As noted above, claim 25, as presented herein, requires affixed to a surface of the tube segment, a **pair of electrodes**. Taylor et al does not disclose a **single**

electrode that is connected to the surface of the tube segment that is **inflatable** to assume a **torus geometry** as required by claim 25. In fact, Taylor et al does not disclose any sort of association between any electrode and any inflatable tube segment that forms an anchor. Nor does Taylor et al disclose a carrier containing either a chemotherapeutic substance or a carrier containing a radioactive substance as required by new claims 29 and 31, respectively.

Applicant therefore respectfully submits that claims 25, 29 and 31 are patentable under 35 U.S.C. § 103(a) over Williamson in view of Taylor et al.

Applicant respectfully requests reconsideration and reexamination of claims 1-11, 13 – 26 and 29 – 31, as presented herein, and submits that these claims are in condition for allowance and should be passed to issue.

If any fee or extension of time is required to obtain entry of this Amendment, the undersigned hereby petitions the Commissioner to grant any necessary time extension and authorizes charging Deposit Account No. 04-1403 for any such fee not submitted herewith.

Respectfully submitted,

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Date:

30 April 2009


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